

REMARKS

As an initial matter, Applicant wishes to thank the Examiner for acknowledging previous claim amendments overcame the objection of Claim 1 and the rejection under 35 U.S.C. §112, second paragraph, of Claim 1, 3, 4, 7, 10, 12-17, and 30.

Claims 1, 3-10, 12-17, 23-25, and 30-32 are pending in this Application with Claims 5, 6, 8, 9, and 23-25 having been withdrawn from consideration by the Examiner. Claims 8-9 and 25 have been cancelled. Upon entry of this Amendment and Response, Claims 1, 3-7, 10, 12-17, 23, 24, and 30-32 will be pending in this Application with Claims 23 and 24 having been withdrawn from consideration by the Examiner.

Double Patenting Rejection

Claims 1, 3, 4, 7, 10, 12-17, and 30 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 6-11, 15, and 34-36 of copending Application No. 10/427,929.

Claims 1, 3, 4, 7, 10, 12-17, and 30 also remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 25, 28, and 29 of copending Application No. 10/669,251.

Applicant respectfully requests that this issue be deferred until allowable subject matter is indicated.

Rejection under 35 U.S.C. §112, first paragraph

As an initial matter, Applicant wishes to thank the Examiner for acknowledging the ambiguity of the previous Office Action in which two different rejections were presented under the first paragraph of 35 U.S.C. §112.

Claims 1, 3, 4, 7, 10, 12-17, and 30-32 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Office Action alleges that:

The issue of enablement - whether or not the specification provides guidance for administering a serine protease inhibitor to a subject adequate for a therapeutic affect by inhibiting apoptosis, is addressed in a following rejection of record.

The specification fails to exemplify or describe the practice of methods of claims 1, 3, 4, 7, 10, 12-17, and 30 wherein a method of administering the elected serine protease inhibitor α -1-antitrypsin to a subject has any affect on the admittedly intracellular pathways of apoptosis ... by inhibiting cellular serine proteases, metalloproteases, or other proteases

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Enclosed herewith are two scientific journal articles, Exhibit A (*The American Journal of Pathology*, **2006**, 169(4), pp. 1155-1166) and Exhibit B (*Am. J. Respir. Crit. Care Med.*, **2006**, 173, pp 1222-1228), that clearly show AAT inhibits apoptosis in lung endothelial cells and pulmonary emphysema, respectively. Accordingly, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, is improper and should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants submit that all claims now pending in this Application are in condition for allowance. Therefore, an early Office Action to that effect is earnestly solicited. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at (303) 955-8103.

Respectfully submitted,

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Date: March 19, 2008

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